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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 121

RIN 0906-AB02

Change to the Definition of “Human Organ” Under Section 301 of the National Organ Transplant Act of 1984; Withdrawal

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Proposed Rule; Withdrawal.

SUMMARY: This document withdraws a proposed rule published in the Federal Register on October 2, 2013. The proposed rule sought public comment on the proposed change in the definition of “human organ” in section 301 of the National Organ and Transplant Act of 1984, as amended, (NOTA) to explicitly incorporate hematopoietic stem cells within peripheral blood in the definition of “bone marrow.” HHS received over 500 comments on the proposed rule. Given the number of substantive comments, at this time HHS has decided to consider the issue further and may issue an NPRM in the future.

DATES: The proposed rule published on October 2, 2013 (78 FR 60810) is withdrawn as of **[INSERT DATE OF FEDERAL REGISTER PUBLICATION]**.

ADDRESSES: Division of Transplantation, 5600 Fishers Lane, Room 8W63, Rockville, MD 20852

FOR FURTHER INFORMATION CONTACT: Frank L. Holloman, MPA, Acting

Division Director, Division of Transplantation, 5600 Fishers Lane, Room 8W63,
Rockville, MD 20852. Telephone: (301) 443-7577.

SUPPLEMENTARY INFORMATION:

On March 1, 2017, President Trump issued Executive Order 13777, “Enforcing the Regulatory Reform Agenda,” to implement and enforce regulatory reform (82 FR 12285 2/24/2017). Executive Order 13777 directed each Federal agency to establish a Regulatory Reform Task Force to identify regulations that are “outdated, unnecessary, or ineffective.” In accordance with guidance from Executive Orders 13777 and 13771 (January 30, 2017, titled “Regulatory Freeze Pending Review”), HHS’s Task Force identified the proposed change in definition of “human organ” as a candidate for withdrawal at this time.

Dated: November 13, 2018.

George Sigounas

Administrator,

Health Resources and Services

Administration.

Dated: November 20, 2018.

Alex M. Azar II

Secretary.

Department of Health and Human Services.

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